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| FEE TRANSMITTAL | | Complete if Known | |
|---|--|------------------------|----------------------|
| Patent fees are subject to annual revision. | | Application Number | 10/042,761 |
| | | Filing Date | January 15, 2003 |
| | | First Named Inventor | A.G. Daifotis et al. |
| | | Examiner Name | To be determined |
| | | Group Art Unit | To be determined |
| | | Attorney Docket Number | 20002YPCI |
| TOTAL AMOUNT OF PAYMENT | | \$180 | |

| METHOD OF PAYMENT (Check one) | | FEE CALCULATION (continued) | |
|--|-----------------------|--|----------------|
| <input checked="" type="checkbox"/> Deposit Account Deposit Account Number: 13-2755 Deposit Account Name: Merck & Co., Inc. The Director is authorized to: <input checked="" type="checkbox"/> Charge fee(s) indicated below <input checked="" type="checkbox"/> Credit any overpayments <input checked="" type="checkbox"/> Charge any additional fee(s) during the pendency of this application | | 3. ADDITIONAL FEES | |
| FEE CALCULATION | | | |
| 1. BASIC FILING FEE | | | |
| Large Fee Code | Entity Fee (\$) | Fee Description | Fee Paid |
| 1001 | 750 | Utility filing fee | |
| 1002 | 330 | Design filing fee | |
| 1004 | 750 | Reissue filing fee | |
| 1005 | 160 | Provisional filing fee | |
| SUBTOTAL(1) | | | \$0 |
| 2. EXTRA CLAIM FEES | | | |
| Total Claims | 20 | Extra | Fee from below |
| Independent Claims | 3 | ** = | 0 |
| Multiple Dependent Claims | | \$280 = | |
| **or number previously paid, if greater; For Reissues, see below | | | |
| Large Fee Code | Entity Fee (\$) | Fee Description | Fee Paid |
| 1202 | 18 | Claims in excess of 20 | |
| 1201 | 84 | Independent claims in excess of 3 | |
| 1203 | 280 | Multiple dependent claim, if not paid | |
| 1204 | 84 | **Reissue independent claims over original patent | |
| 1205 | 18 | **Reissue claims in excess of 20 and over original patent | |
| SUBTOTAL(2) | | | \$0 |
| | | 3. ADDITIONAL FEES (continued) | |
| Fee Code | Large Entity Fee (\$) | Fee Description | Fee Paid |
| 1051 | 130 | Surcharge - late filing fee or oath | |
| 1812 | 2,520 | For filing a request for <i>ex parte</i> reexamination | |
| 1251 | 110 | Extension for reply within first month | |
| 1252 | 410 | Extension for reply within second month | |
| 1253 | 930 | Extension for reply within third month | |
| 1254 | 1,450 | Extension for reply within fourth month | |
| 1255 | 1,970 | Extension for reply within fifth month | |
| 1401 | 320 | Notice of Appeal | |
| 1402 | 320 | Filing a brief in support of an appeal | |
| 1403 | 280 | Request for oral hearing | |
| 1452 | 110 | Petition to revive - unavoidable | |
| 1453 | 1,300 | Petition to revive - unintentional | |
| 1501 | 1,300 | Utility issue fee (or reissue) | |
| 1502 | 470 | Design issue fee | |
| 1460 | 130 | Petitions to the Commissioner | |
| 1807 | 50 | Processing fee under 37 CFR 1.17(q) | |
| 1806 | 180 | Submission of Information Disclosure Statement | 180 |
| 8021 | 40 | Recording each patent assignment per property (times number of properties) | |
| 1809 | 750 | Filing a submission after final rejection (37 CFR 1.129(a)) | |
| 1810 | 750 | For each additional invention to be examined (37 CFR 1.129(b)) | |
| 1801 | 750 | Request for Continued Examination (RCE) | |
| Other fee (specify) | | | |
| Other fee (specify) | | | |
| SUBTOTAL(3) | | | \$180 |

| SUBMITTED BY | | | Complete (if applicable) | |
|-----------------------|-------------------------|---------|--------------------------|--------|
| Typed or Printed Name | J. Antonio Garcia-Rivas | | Reg. Number | 42,567 |
| Signature | | | Deposit Account User ID | |
| | Date | 8/14/03 | | |

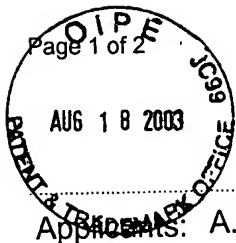
Application Number: 10/042,761
Filing Date: 01/15/2003
First Named Inventor: A.G. Daifotis et al.
Group Art Unit: To be determined
Examiner Name: To be determined
Attorney Docket Number: 20002YPCI

FIRST CLASS MAIL CERTIFICATE

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450, ON THE DATE APPEARING BELOW.

MERCK & CO., INC.

MAILED BY Barbara Muller DATE 8-14-03



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: A.G. DAIFOTIS et al.

Serial No. 10/042,761

Filed: January 15, 2003

For: METHOD FOR INHIBITING BONE
RESORPTION

Art Unit: To be determined

Examiner: To be determined

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application.

This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

08/20/2003 JADD01 00000051 132755 10042761
01 FC:1806 180.00 DA

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By Barbara Muller Date 8-14-03

**INFORMATION DISCLOSURE STATEMENT**

4. Except for Cite Nos. 96-116, copies of the references listed on the attached form are not enclosed because they have been submitted to or cited by the Office in a related application as follows:

| RELATED APPLICATION | | |
|---------------------|-----------------|------------|
| U. S. SERIAL NUMBER | FILING DATE | MERCK CASE |
| 09/376,315 | August 18, 1999 | 20002YPCB |
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upon which the instant application relies for an earlier filing date under 35 U.S.C. 120. Therefore, pursuant to 37 C.F.R. 1.98(d), copies of these references are not enclosed herewith. If this is inconvenient, additional copies will be submitted upon request.

5. In accordance with 37 C.F.R. 1.97, (check one)

- ☐ the attached information is filed within three months of the filing date of the captioned case.
- ☒ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ the undersigned certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,

By: J. Antonio Garcia-Rivas

Attorney _____ For Applicant(s)

Reg. No. 42,567

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594-1513

Date: August 14, 2003



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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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| Filing Date | January 15, 2003 |
| First Named Inventor | A.G. Daifotis |
| Group Art Unit | To be determined |
| Examiner Name | To be determined |
| Attorney Docket Number | 20002YPCI |

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY |
|-----------------------|-------------|----------------------|----------------------------|--|--|
| | | Number | Kind Code (if known) | | |
| | 1 | 5,270,365 | | Gertz et al. | 12/14/1993 |
| | 2 | 5,366,965 | | Strein | 11/22/1994 |
| | 3 | 4,761,406 | | Flora et al. | 08/02/1988 |
| | 4 | 4,425,339 | | Pitchford | 01/10/1984 |
| | 5 | 4,621,077 | | Rosini et al. | 11/04/1986 |
| | 22 | 5,616,560 | | Geddes | 04/01/1997 |
| | 23 | 5,780,455 | | Brenner et al. | 07/14/1998 |
| | 24 | 5,773,429 | | Fuisz | 06/30/1998 |
| | 27 | 5,488,041 | | Barbier et al. | 01/30/1996 |
| | 28 | 4,980,171 | | Fels et al. | 12/15/1990 |
| | 40 | 4,812,304 | | Anderson et al. | 03/14/1989 |
| | 41 | 4,822,609 | | Flora | 04/18/1989 |
| | 48 | 5,358,941 | | Bechard et al. | 10/25/1994 |
| | 49 | 5,616,571 | | Daifotis et al. | 04/01/1997 |
| | 50 | 5,853,759 | | Katdare et al. | 12/29/1998 |
| | 51 | 5,804,570 | | Santora II et al. | 09/08/1998 |
| | 58 | 5,583,122 | | Benedict et al. | 12/10/1996 |
| | 59 | 5,622,721 | | Dansereau et al. | 04/22/1997 |
| | 60 | 4,927,814 | | Gall et al. | 05/22/1990 |
| | 63 | 5,994,329 | | Daifotis et al. | 11/30/1999 |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY |
|-----------------------|-------------|-------------------------|-----------------|----------------------------|--|--|
| | | Office | Number | Kind Code (if known) | | |
| | 6 | | WO 95/30421 | | Goodship et al. | 11/16/1995 |
| | 7 | | WO 96/17616 | | Gazard | 06/13/1996 |
| | 8 | | WO 94/00129 | | Francis et al. | 01/06/1994 |
| | 9 | | WO 94/00130 | | Hovancik et al. | 01/06/1994 |
| | 10 | | WO 94/21242 | | D'Souza et al. | 09/29/1994 |
| | 25 | | WO 95/28145 | | Shinoda et al. | 10/26/1995 |
| | 26 | | EP 0 600 834 A1 | | Goodship et al. | 08/06/1994 |
| | 37 | | EP 0 274 158 | | Ebetino et al. | 07/13/1988 |
| | 38 | | WO 95/08331 | | Bechard | 03/30/1995 |
| | 39 | | WO 95/28936 | | Yates | 11/02/1999 |

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| First Named Inventor | A.G. Daifotis |
| Group Art Unit | To be determined |
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OTHER NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. | Include name of the author, title, date, page(s), volume-issue number(s) and place of publication. |
|--------------------|----------|---|
| | 11 | Lunar News, April 1997, "Update: Bisphosphonate", pp. 30-32 |
| | 12 | Gertz et al., Osteoporosis Int. (1993), Suppl. 3: S13-16, "Clinical pharmacology of alendronate sodium" |
| | 13 | Gertz et al., Clin. Pharma. Ther. (1995), Vol. 58, pp. 288-98, "Studies of the oral bioavailability of alendronate" |
| | 14 | de Vernejoul et al., Calcified Tissue Int'l, Vol. 40 (1987), pp. 160-165, "Different schedules of administration of (3 amino-1-hydroxypropylidene)-1,1-bisphosphonate induce different changes ..." |
| | 15 | Lufkin et al., Osteoporosis Int'l. (1994), Vol. 4, pp. 320-322, "Pamidronate: An unrecognized problem in gastrointestinal tolerability". |
| | 16 | De Groen et al., N. England J. of Medicine, (1996), Vol. 335, pp. 1016-1021, "Esophagitis associated with the use of alendronate" |
| | 17 | Castell, (an editorial), N. England J. of Medicine (1996), Vol. 335, pp. 1058-1059, "Pill esophagitis - the case of alendronate". |
| | 18 | Liberman et al., (correspondence), N. England J. of Medicine (1996), Vol. 335, pp. 1069-1070, "Esophagitis and alendronate". |
| | 19 | Chesnut et al., Am. J. of Medicine, Vol. 99 (1995), pp. 144-152, "Alendronate treatment of the postmenopausal osteoporotic woman ...". |
| | 20 | Cassidy et al., Digestive Diseases and Sciences, Vol. 37 (1992), pp. 1206-1211, "Continuous versus intermittent acid exposure in production of esophagitis in feline model". |
| | 21 | Mortensen et al., J. of Bone & Mineral Res., (1995) Vol. 10, suppl. 1, p. s140, "Prevention of early postmenopausal bone loss of risendronate". |
| | 29 | Singer et al., Advances in Endocrin.& Metab., Vol. 6 (1995), pp. 259-288, "Bisphosphonates in the treatment of disorders or mineral metabolism". |
| | 30 | Lieberman et al., N. Eng. J. of Medicine, Vol. 333 (1995), pp. 1437-1443, "Effect of oral alendronate on bone mineral density and the incidence of fractures in postmenopausal osteoporosis". |
| | 31 | Bankhurst et al., Arthritis and Rheumatism, Vol. 38, No. 9, Suppl. 1 (1995), S359, "Three-year treatment with alendronate prevents fractures in women with postmenopausal osteoporosis". |
| | 32 | Filipponi et al., J. of Bone & Min. Research, Vol. 10 (1995), pp. 697-703, "Cyclical clondronate is effective in preventing postmenopausal bone loss: A comparative study with transcutaneous hormone replacement therapy". |

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| Group Art Unit | To be determined |
| Examiner Name | To be determined |
| Attorney Docket Number | 20002YPCI |

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OTHER NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. | Include name of the author, title, date, page(s), volume-issue number(s) and place of publication. |
|--------------------|----------|---|
| | 33 | McClung et al., Bone, Vol. 17 (1995), pp. 493S-496S, "Tiludronate therapy for Paget's disease of bone". |
| | 34 | Seltenmeyer et al., Bone (NY), Vol. 20, No. 4, Suppl., (1997) pp. 114S, "A comparison of the antiresorptive potency of various bisphosphonates in vivo with their inhibitory effect in vitro on squalene synthase and cellular sterol synthesis". |
| | 35 | Adachi et al., Today's Therapeutic Trends, Vol. 14, No. 1 (1996), pp. 13-24, "Osteoporosis -- its diagnosis, management and treatment with a new oral bisphosphonate agent, etidronate". |
| | 36 | Bell et al., Endocrine, Vol. 6(2) (1997), pp. 203-206, "Bisphosphonates in the Treatment of Osteoporosis". |
| | 42 | Melsen et al., Osteoporosis, Chapt. 60(1996), pp. 1145-1158, "ADFR - The Concept and its performance". |
| | 43 | Thompson et al., J. of Bone & Min. Research, Vol. 7(1992), pp. 951-960, "The bisphosphonate, alendronate, prevents bone loss in ovariectomized baboons". |
| | 44 | Balena et al., J. Clin. Invest., Vol. 92 (1993), pp. 2577-2586, "The effects of 2-year treatment with the aminobisphosphonate alendronate on bone metabolism, bone histomorphometry, and bone strength in ovariectomized nonhuman primates". |
| | 45 | Peter et al., Digestive Diseases & Sciences, Vol. 43 (1998), pp. 1009-1015, "Comparative study of potential for bisphosphonates to damage gastric mucosa of rats". |
| | 46 | Peter et al., Digestive Diseases & Sciences, Vol. 43 (1998), pp. 1998-2002, "Esophageal irritation due to alendronate sodium tablets". |
| | 47 | Harris et al., J. of Clin. Endoc. & Metab., 76:1399-1406 (1993), "The effect of short term treatment with alendronate on vertebral density and biochemical markers of bone...". |
| | 52 | Khan et al., Bone, Vol. 20 (1997), pp. 263-271, "Alendronate in the treatment of Paget's disease of bone". |
| | 53 | Physician's Desk Reference, 51st ed. (1997), pp. 1703-1706, "Fosamax". |
| | 54 | Gertz et al., J. of Bone & Min. Res., Vol. 9 (1994), pp 135-142, "Monitoring bone resorption in early postmenopausal women by an immunoassay for cross-linked collagen peptides in urine". |
| | 55 | Fleisch, J. of Clin. Endoc. & Metab., Vol. 76 (1993), pp. 1397-1398, "Editorial: Prospective use of bisphosphonates in osteoporosis". |
| | 56 | Chesnut et al., Osteoporosis Int'l (1993), Suppl. 3: S17-19, "Short-term effect of alendronate on bone mass and bone remodeling in postmenopausal women". |

Examiner
SignatureDate
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Sheet 5 of 8

OTHER NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. | Include name of the author, title, date, page(s), volume-issue number(s) and place of publication. |
|--------------------|----------|---|
| | 57 | Gertz et al., J. of Bone & Min. Res., Vol. 6, Suppl. 1 (1991), Abstract No. 790, p. S281, "Oral bioavailability and dose proportionality of alendronate (aminohydroxybutylidene bisphosphonate) in postmenopausal women". |
| | 61 | Mortensen et al., J. Bone & Min. Res., (1995), 10 (Supp. 1): S360, "Prevention of early postmenopausal bone loss by residronate: A two year study". |
| | 62 | Actonel™ (risedronate sodium tablets) package insert, dated March 1998. |
| | 68 | Lunar News (July 1996), "Update: Bisphosphonate", pp. 23-24 |
| | 69 | Lunar News (April 1996), "Update: Bisphosphonate", p. 31 |
| | 70 | The Pink Sheet (Dec. 18, 1995), Vol. 57, Issue 51, "Merck Cozaar generating 25,000 scripts weekly after six months on market; Foxamax off to quick start, company tells securities analyst meeting". |
| | 71 | Scrip (11/24/99), "Merck develops once-weekly Fosamax". |
| | 72 | Baran, Geriatrics, Vol. 56, No. 3 (March 2001), pp. 28-32, "Osteoporosis: Efficacy and safety of a bisphosphonate dosed once weekly". |
| | 73 | Bone et al., Clinical Therapeutics, Vol. 22, No. 1 (2000), pp. 15-28, "Weekly administration of alendronate: Rationale and plan for clinical assessment". |
| | 74 | Fleisch, Expert Opinion Therapeutic Patents, Vol. 11, No. 9 (2000), p. 1371-1381, "Bisphosphonates: mechanisms of action". |
| | 75 | Peter et al., Journal of Pharmacology & Experimental Therapeutics, Vol. 276, No. 1 (1996), p. 271-276, "Long-term safety of the aminobisphosphonate alendronate in adult dogs". |
| | 76 | Rodan et al., Osteoporosis International (1993) Suppl., 3:S7-12, "Preclinical Pharmacology of alendronate". |
| | 77 | Schnitzer, Expert Opinion Pharmacother., Vol. 2, No. 9 (2001), pp. 1461-1472, "Update on alendronate for osteoporosis: once-weekly dosing". |
| | 78 | Schnitzer et al., Aging: Clinical and Experimental Research, Vol. 12, No. 1 (2000), P. 1-12, "Therapeutic equivalence of alendronate 70 mg once-weekly and alendronate 10 mg daily in the treatment of osteoporosis". |
| | 79 | Seedor et al., Journal of Bone & Mineral Research, Vol. 6, No. 4 (1991), pp. 339-346, "The bisphosphonate alendronate (MK-217) inhibits bone loss dur to ovariectomy in rats". |

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OTHER NON PATENT LITERATURE DOCUMENTS

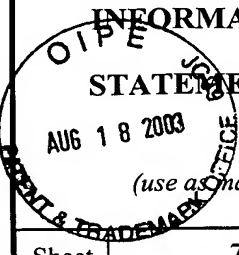
| Examiner Initials* | Cite No. | Include name of the author, title, date, page(s), volume-issue number(s) and place of publication. |
|--------------------|----------|--|
| | 80 | Sorrentino, Endoscopy, Vol. 28 (1996), p. 529, "Esophageal ulceration due to alendronate". |
| | 81 | Blank, American College of Gastroenterology 66th Annual Scientific Meeting, "Lack of gastric adaptation to weekly versus daily alendronate administration in rats". |
| | 82 | Bone et al., Journal of Bone & Mineral Research, Vol. 16, Suppl. 1 (September 2001), M392, "Once-weekly alendronate: Two year subgroup efficacy analyses in postmenopausal women with osteoporosis". |
| | 83 | Bone III et al., 6th International Symposium on Clinical Disorders of Bone and Mineral Metabolism, Venice, Italy, November 20-25, 1999, "Alendronate 70 mg once weekly is therapeutically equivalent to alendronate in 10 mg daily". |
| | 84 | Brown et al., Journal of Bone & Mineral Research, Vol. 16, Suppl. 1 (September 2001), M402, "Efficacy, safety and tolerability of once weekly (80 mg vs. 160 mg) oral alendronate in postmenopausal osteoporosis". |
| | 85 | Delaney et al., ENDO 2001, The Endocrine Society's 83rd Annual Meeting, Denver, Colorado (June 2001), Abstract, P1-469 (June 2001), p. 249, "Bone density changes in response to risedronate once weekly". |
| | 86 | Gordon et al., ENDO 2001, The Endocrine Society's 83rd Annual Meeting, Denver, Colorado (June 2001), Abstract, P1-460 (June 2001), p. 247, "Weekly administration of risedronate increase bone mineral density". |
| | 87 | Lindsay et al., Arthritis & Rheumatism, Vol. 44, No. 9 (Suppl.), Abstract No. 604, "Risedronate 35 mg once a week is as effective as 5 mg daily in postmenopausal women". |
| | 88 | Rizzoli et al., Journal of Bone & Mineral Research, Vol. 16, Suppl. 1 (September 2001), M401, "Two year results of once-weekly administration of alendronate 70 mg for the treatment of postmenopausal osteoporosis". |
| | 89 | Rizzoli et al., Annals of the Rheumatic Diseases, Annual European Congress of Rheumatology, EULAR 2001, Prague, Czech Republic, Vol. 60, Suppl. 1 (July 2001), Abstract SAT0164, p. 256, "Two year results of once-weekly administration of alendronate 70 mg for the treatment of postmenopausal osteoporosis". |
| | 90 | Van Dyke, et al., Annals of the Rheumatic Diseases, Annual European Congress of Rheumatology, EULAR 2001, Prague, Czech Republic, Vol. 60, Suppl. 1 (July 2001), Abstract SAT0167, p. 256, "Safety of once-weekly alendronate 70 mg in periodontal disease". |
| | 91 | Wimalawansa, Journal of Bone & Mineral Research, Vol. 16, Suppl. 1 (September 2001), Abstract SA352, "Once a week alendronate therapy: A convenient and effective way of prevention and treatment of osteoporosis: A four-year clinical study". |
| | 92 | Wimalawansa, Journal of Bone & Mineral Research, Vol. 16, Suppl. 1 (September 2001), Abstract SU399, "Efficacy of once a week risedronate in comparison with once-weekly alendronate therapy for postmenopausal osteoporosis: One-year data". |
| | 93 | Wimalawansa, ENDO 2001, The Endocrine Society's 83rd Annual Meeting, Denver, Colorado (June 2001), Abstract P1-438, p. 241-242, "Highly efficacious and cost-effective alendronate regimen for postmenopausal osteoporosis: A four-year clinical study" |
| | 94 | Woodson, Osteoporosis International, Vol. 11, Suppl. 2 (2000), Chicago, Illinois, p. S204, Abstract 550 (514), "Once weekly risedronate therapy". |

Examiner
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Considered

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| Substitute for form 1449A/PTO | | | COMPLETE IF KNOWN | | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (use as many sheets as necessary) | | | Application Number | 10/042,761 | |
| | | | Filing Date | January 15, 2003 | |
| | | | First Named Inventor | A.G. Daifotis | |
| | | | Group Art Unit | To be determined | |
| | | | Examiner Name | To be determined | |
| Sheet | 7 | of | 8 | Attorney Docket Number | 20002YPCI |

| OTHER NON PATENT LITERATURE DOCUMENTS | | |
|---------------------------------------|----------|--|
| Examiner Initials* | Cite No. | Include name of the author, title, date, page(s), volume-issue number(s) and place of publication. |
| | 99 | Men's Osteoporosis Support Group, Vol. 1, Issue 2, 1 July 1997 |
| | 100 | Rote List 1997, 66 023 (Fosamax) |
| | 101 | Reddy M.S. et al, J. Periodontol, 1995, Vol. 66(3), pp. 211-217, "Alendronate Treatment of Naturally-Occurring Periodontitis in Beagle Dogs". |
| | 102 | Fleisch H., "Bisphosphonates in Bone Disease from the Laboratory to the patient", 1995 (Book) |
| | 103 | Black D.M. et al., The Lancet, 1996, 348, pp. 1535-1541, "Randomised trial of effect of alendronate on risk of fracture in women with existing vertebral fractures". |
| | 104 | Affidavit of Gideon Rodan from validity trial of IL 94612 dated 17 Nov. 2000 |
| | 105 | Merck & Co., Inc. - Instructions for Once Weekly Fosamax, January 2001 |
| | 106 | Lombardi et al., Ann. Ital. Med. Int. 7, 1992, 3 Suppl., pp. 158-165, "Clinical trials with bisphosphonates" |
| | 108 | Reid et al, American Journal of Medicine, 1996, Vol. 101, pp. 341-348, "Biochemical and Radiologic Improvement in Paget's Disease of Bone Treated with Alendronate: A Randomized, Placebo-controlled Trial". |
| | 109 | Passeri et al, Bone and Mineral, 1991, Vol. 15, pp. 237-248, "Intermittent treatment with intravenous 4-amino-1-hydroxybutylidene-1,1-bisphosphonate (AHBuBP) in the therapy of postmenopausal osteoporosis". |
| | 110 | Devogelaer et al, Bone, 1996, Vol. 18(2), pp. 141-150, "Oral Alendronate Induces Progressive Increases in Bone Mass of the Spine, Hip, and Total Body Over 3 Years in Postmenopausal Women with Osteoporosis". |
| | 111 | Siris et al, J. Clin. Endo. Metab., 1996, Vol. 81(3), pp. 961-967, "Comparative Study of Alendronate Versus Etidronate for the Treatment of Paget's Disease of Bone". |
| | 112 | Toolan et al, J. Bone Min. Res., 1992, Vol. 3, pp. 1399-1406, "Effects of 4-Amino-1-Hydroxybutylidene Bisphosphonate on Bone Biomechanics in Rats". |
| | 113 | Balena et al, Bone, 1993, Vol. 14, pp. 499-504, "the Aminobisphosphonate Alendronate Inhibits Bone Loss Induced by Thyroid Hormone in the Rat Comparison Between Effects on Tibiae and Vertebrae". |
| | 114 | Fleisch et al, Hormone and Metabolic Research, Vol. 29 (1997), pp. 145-150, "Bisphosphonates: Mechanisms of Action and Clinical Use in Osteoporosis - An Update". |

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|--------------------|--|-----------------|--|
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